UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

THE JOHNSON & JOHNSON DEFENDANTS'
MEMORANDUM IN SUPPORT OF THEIR MOTION
FOR SUMMARY JUDGMENT AS TO CLASS 1 AND CLASS 2

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MISCELLANEOUS

Johnson & Johnson, Ortho Biotech Products, L.P., and Centocor, Inc. (the "J&J Defendants") respectfully submit this Memorandum of Law in Support of their Motion for Summary Judgment as to the two Medicare classes certified by the Court. Based on the undisputed facts, neither of these classes, nor the individual class representatives, will be able to prove that the J&J Defendants engaged in "AWP fraud." The J&J Defendants should be dismissed.

PRELIMINARY STATEMENT

Only two of Johnson & Johnson's physician-administered drugs remain at issue in this case, Procrit®, which is sold by Ortho Biotech, and Remicade®, which is sold by Centocor. By plaintiffs' own admission, the "spreads" on both drugs were modest. In fact, when certain known errors in plaintiffs' "spread" calculations are corrected, the differences between the published AWPs for these drugs and their average selling prices ("ASPs") were 30% or less. Drugs with spreads that modest have no place in this litigation.

Plaintiffs premised this litigation on two fundamental contentions: first, that manufacturers misled payors by reporting fictitious, inflated AWPs instead of actual selling prices, and second, that the published AWPs for the physician-administered drugs selected for inclusion in the Complaint were so divorced from actual selling prices that their spreads, unlike the spreads on other drugs, could fairly be described as "mega-spreads." Plaintiffs cited examples of spreads ranging between 230% and 20,735%. Fourth Amended Master Consolidated Class Action Complaint ("Complaint"), ¶ 200.

These two contentions encountered one basic problem – they weren't true. Plaintiffs quickly jettisoned the first contention when payors began testifying that they never thought that the published AWPs were equal to ASPs. The second contention collapsed when plaintiffs

obtained defendants' pricing data and learned that the spreads on a number of the physician-administered drugs listed in the Complaint, including Procrit and Remicade, did not match plaintiffs' rhetoric.

With both legs of the case knocked out from beneath them, plaintiffs came up with a fall back position for Class 3. Their new theory, as espoused by their expert, Dr. Raymond S. Hartman, is that payors "expected" there to be a "predictable relationship" between AWP and ASP. At his recent deposition, Dr. Hartman testified that the upper bound of the payors' expectation is like a "speed limit." He finds fraud whenever the percentage difference between AWP and ASP goes past the limit.

For Class 1 and Class 2, Dr. Hartman was asked by plaintiffs' counsel to assume that "speed limit" was zero, *i.e.*, that AWP was supposed to equal ASP as a matter of law.[1] For Class 3, Dr. Hartman originally testified that private payors expected AWP to exceed ASP by 33%. He now thinks that the "speed limit" should be 30%.[2]

Defendants' joint brief demolishes the argument that Congress or CMS intended the speed limit to equal "zero," *i.e.*, that AWP equaled ASP, or that the government expected there to be a "predictable relationship" between the two. Defendants are entitled to summary judgment on the Class 1 and Class 2 claims on that basis alone.

We assume for purposes of this motion, however, that plaintiffs will abandon the theory that AWP equals ASP for Classes 1 and 2, and that they will be argue, in the alternative, that Dr.

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[1] Deposition of Raymond S. Hartman ("Hartman Dep.") at 661-63 (Vol. III: Feb. 27, 2006) & 1236-37 (Vol. V: Mar. 1, 2006) (Declaration of Andrew D. Schau ("Schau Decl.") submitted herewith, Exhibit 1).

[2] *Compare* Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification (Sept. 3, 2004) (hereinafter "Hartman Class Cert. Report"), ¶¶ 30(g), 33(b) (33%) (Schau Decl., Exh. 2) *with* Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages (Dec. 15, 2005), ¶ 59(e) (hereinafter "Hartman Liability Report") (30%) (Schau Decl., Exh. 3).

Hartman's "30% expectation" theory applies to these classes as well. Indeed, Dr. Hartman testified that the government's expectations were no different than the expectations of private insurers. *See* Hartman Dep. at 672 ("The government has set reimbursement rates that reflect an understanding that is comparable to what I would say is the -- in my yardsticks.")

If plaintiffs adopt this argument, the J&J Defendants will still be entitled to summary judgment. The spreads on Procrit and Remicade are not "mega-spreads" and there is no possibility that payors were deceived by the J&J Defendants' published list prices and AWPs.

Plaintiffs have repeatedly characterized their claims as being limited to drugs with "mega-spreads." The Court noted this in its class certification ruling:

> Plaintiffs claim that "defendants (or wholesalers) sell a drug to retailers at a net price significantly below the expected 'AWP minus 16% to 33%' threshold . . . .[3]

The disconnect between plaintiffs' "mega-spread" theory and the J&J Defendants' pricing became apparent at the class certification hearing:

MR. CAVANAUGH:	Here's Remicade, your Honor. It's a 30 percent spread. It actually comes in within . . . Dr. Hartman's supposed expectation, which he says is 17 to 33 percent.
THE COURT:	***Okay, that's good one for you.*** Are there certain drugs that would be somewhere, I imagine --
MR. CAVANAUGH:	Absolutely. That goes to my point, your Honor. It's going to require that type of individualized inquiry: What did you expect with respect to [Taxol]? What did you expect with respect to Remicade?
THE COURT:	***Why can't I throw out these kind of drugs and try the ones where there's a dramatic spread?***[4]

[3] *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 69 (D. Mass. 2005) (Memorandum and Order Re: Motion for Class Certification) (emphasis in original). The Court's formulation expresses the spread as a discount below AWP. Dr. Hartman expresses it as premium over the selling price. For example, if the selling price of a drug is 16% to 33% below its AWP, the AWP would be 19% to 49% above the selling price.

Plaintiffs should have dropped the J&J Defendants from the case as soon as they realized how small the Procrit and Remicade "spreads" were. But sales on these two medicines are in the billions of dollars, and plaintiffs had already selected the J&J Defendants for inclusion in Track 1. They decided to press forward regardless of the facts.

If class action litigation and discovery were not so expensive, plaintiffs' maneuverings to keep the J&J Defendants in the case would be almost comical. For starters, Dr. Hartman simply changed his mind about payor expectations. Payor expectations are no longer 33%; now they are 30%.

Lowering the supposed "speed limit" enabled plaintiffs to maintain their claim that Centocor engaged in a fraud, because, according to Dr. Hartman, the "true" Remicade spread on sales to physicians exceeded the published 30% figure. For example, Dr. Hartman alleges that Remicade's spread was 30.8% in one year and 31.9% in another year. These small, incremental differences are alleged to have resulted in widespread deception.

But the small differences identified in Dr. Hartman's Liability Report are illusory. It is undisputed that Centocor never gave rebates or discounts to physicians. In order to get Remicade over Dr. Hartman's 30% speed limit, his staff deviated from Dr. Hartman's instructions as to how the spread should be calculated.

Plaintiffs' calculations of the spread on Procrit are even more disingenuous. In order to portray Procrit's "spreads" as excessive, Dr. Hartman disassembled Procrit's pricing data for each of Procrit's individual NDCs for each year in which it was sold. This resulted in 116 separate "spreads" on the 15 different Procrit NDCs sold between 1991 and 2003. The "fraud," according to plaintiffs, is that the spreads on 16 of these 116 NDCs were greater than 30% (8 of

[4] Class Certification Hearing before the Honorable Patti B. Saris, U.S.D.J., at 76:2-76:13 (Feb. 10, 2005) (emphasis added) (Schau Decl., Exh. 4).

which were between 30% and 33%). *See* Hartman Liability Report, Attachment G.4.c. Thus, plaintiffs allege that there was fraud in a year in which 10 out of 11 of Procrit's NDCs were below 30%, and in another instance where only one individual Procrit NDC was above 30% in only one out of the 11 years it was on the market.

When the spread calculations performed by Dr. Hartman's staff are redone correctly according to Dr. Hartman's intended methodology, taking out the sales Dr. Hartman said should be excluded from his calculations, only one out of 116 Procrit spreads exceeded 30%. Most are below 25%. Declaration of Jayson S. Dukes ("Dukes Decl."), ¶ 30, Exh. 6.

But even if one were to accept Dr. Hartman's uncorrected calculations at face value, spreads of this magnitude hardly represent the sort of "dramatic" spreads which this Court was led to believe this case was really about. The Procrit and Remicade spreads are simply too modest to have deceived anyone, and, as such, are not actionable under the applicable laws of Oklahoma, Nevada, and Massachusetts.

The individual claims asserted by the class representatives fare no better. There is no evidence that either of the named representatives paid for Procrit or Remicade based on AWP. There is no admissible evidence that the Procrit class representative, James Shepley, even received Procrit. To the contrary, his medical records show that he received "Epogen," an identical drug manufactured and sold by Amgen, Inc. Not only can Mr. Shepley not prove that he received Procrit, he cannot prove that he received one of the small number of Procrit NDCs that plaintiffs claim was above 30%, as opposed to one of the larger number of NDCs that they admit were below 30%. The Remicade Class representative has similar flaws. Thus, the class representative claims must be dismissed.

To put it simply, the J&J Defendants do not belong in this case. Their conduct cannot be squared with plaintiffs' allegations. Indeed, as one prominent AWP-relator plaintiff and industry critic told the United States Congress in September 2001, Johnson & Johnson stands apart:

> [AWP has] been around, sir, for the better part, that I'm aware of, about 40 years. And for a great number of those years, it's always worked, and there are still a great number of companies, Merck, Lilly, ***Johnson & Johnson***, DuPont, ***who do not engage in this type of gaming the system***.[5]

I. PLAINTIFFS CANNOT MAKE OUT A PRIMA FACIE CASE OF "AWP FRAUD" RELATING TO PROCRIT

A. Congress Knew Before Procrit Was Launched That AWP Exceeded Actual Transaction Prices

Ortho Biotech launched Procrit in 1991, 18 months after Amgen first began selling Epogen. Declaration of Thomas C. Hiriak ("Hiriak Decl."), ¶ 15. By the time Procrit came to market, Congress already had undertaken to consider different options as to how epoetin alfa should be reimbursed under Medicare, including options unrelated to AWP.

In May 1990, the Office of Technology Assessment for the United States Congress ("OTA") gave Congress a report entitled "Recombinant Erythropoietin: Payment Options for Medicare" (May 1990) (Schau Decl., Exh. 6). The report was prepared in response to a request from the House Ways and Means Committee, Subcommittee on Health, for an analysis of "alternative payment policies that Medicare might adopt to pay for [epoetin alfa]."

The OTA report lays out several different reimbursement options. One of the available reimbursement options was to continue to pay for epoetin alfa administered in a physician's office based on AWP. The OTA report states that Medicare carriers were already using the

[5] Zachary T. Bentley, President, Ven-A-Care, "Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers," Joint Hearing Before the Subcommittee on Health and the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, September 21, 2001, Serial No. 107-65, at 54-55 (emphasis added) (Schau Decl., Exh. 5).

AWP for Amgen's Epogen to derive "an approved charge for physicians who administer recombinant erythropoietin in their offices." OTA Report at 21. Congress was also told that AWPs were "list prices instead of transaction prices that providers actually pay for pharmaceuticals." *Id.* The OTA predicted that when competitors like Ortho Biotech entered the market they would offer "price concessions and other benefits" in order to overcome Epogen's "brand loyalty" from being the "first brand on the market." *Id.* at 71.

Following receipt of the OTA report, Congress did not tell Medicare to change the way it reimbursed physicians who administered epoetin alfa in their offices. Procrit was launched in 1991 with the standard 20% AWP markup over the list price. As the OTA predicted, Ortho Biotech offered price concessions in order to combat Epogen's accrued brand loyalty. The government had no reason to expect anything different.

Given this history, Ortho Biotech could not have proposed that Procrit's published AWP should be equal to the average selling price when it launched the product in 1991. Epogen's AWP was already established at 120% of its list price. Had Procrit's published AWP been the same as its actual acquisition price, physicians would have been unwilling to consider using it. *See* Report of Independent Expert Prof. Ernst R. Berndt to Judge Patti B. Saris, ¶ 24 (Feb. 9, 2005) (a manufacturer introducing a newly approved drug would find it "quite challenging if not impossible" to set the AWP at a small margin over list price) (Schau Decl., Exh. 7). Moreover, state Medicaid agencies were reimbursing pharmacies at rates below AWP.[6] Had Procrit's AWP been equal to the acquisition price, Medicaid providers would have lost money.

[6] *See* Memorandum from HCFA, Region VI to Office of the Director, Bureau of Eligibility, Reimbursement and Coverage, HHS (March 10, 1988) Declaration of Lucy Fowler , ¶ 9, Exh. 8.

B. Procrit's Pricing Was Not Unlawful

1. Procrit's Spreads Were Modest

From the time Ortho Biotech first introduced Procrit in 1991, the "published spread" between Procrit's published AWP and its published list price has been 20%.[7] Over the years, Procrit has offered small discounts to retail drug stores (discontinued in 1999) and to physicians.[8] The explanations for these discounts are set out in Mr. Hiriak's Declaration. The undisputed evidence is that these discounts did not result in the types of spreads plaintiffs have been touting from the outset of this case. In fact, they do not even exceed Hartman's 30% speed limit. Dukes Decl., ¶ 30, Exh. 6.

Dr. Hartman's own calculations starkly rebut plaintiffs' claim that payors were deceived by Procrit's spreads. He calculates 116 separate "spread" figures based on each Procrit NDC for each year. ***According to Dr. Hartman's calculations, 100 of Procrit's 116 alleged spreads (86%) were 30% or less.*** *See* Hartman Liability Report, Attachment G.4.c. Most of the spreads that he says exceeded 30%, exceeded it only slightly.[9] Most of Procrit's spreads are less than 25%. Dukes Decl., ¶ 27, Exh. 4.

These modest spreads are nothing like the "mega-spreads" that this case – as plaintiffs said from the outset – is supposed to be about. Moreover, there is no discernable pattern as to which of Procrit's NDCs allegedly exceeded 30% and which did not. Some NDCs ***never***

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[7] Plaintiffs' Supplemental Response to J&J Defendants' Requests for Admission and Interrogatories Concerning Procrit, Exhibit A (Dec. 13, 2005) (Schau Decl., Exh. 8)

[8] Procrit is somewhat unusual in that it is carried by retail drug stores and physicians. Hiriak Decl., ¶ 18.

[9] Hartman initially reported three anomalous spreads that were greater than 50%, including one that was 221.3%. Hartman Liability Report, Attachment G.4.c. These anomalous spreads do not appear in Dr. Hartman's Supplemental Report. *See* Supplemental Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages ("Hartman Supplemental Report") dated February 3, 2006, Attachment G.4.c (Schau Decl., Exh. 9).

exceeded 30%, in any of the years they were sold, whereas other NDCs exceeded it only once or twice. Only two NDCs allegedly exceeded 30% three times, and even those two NDCs usually did not exceed 30%. Hartman Liability Report, Attachment G.4.c.

There is also no pattern as to when Procrit's NDCs allegedly exceeded 30% and when they did not. In 1991, 1992, 1994, 2000, and 2001, ***none*** of Procrit's spreads exceeded 30%. In 1993, two out of 11 NDCs had spreads that allegedly exceeded 30%. In 1995, only one spread on one NDC allegedly exceeded 30% (by a mere 0.3%), but that NDC's spread was less than 30% in all other years between 1991 and 2003. In short, as shown in the following table, the random distribution of the spreads alleged to exceed 30% refutes Dr. Hartman's thesis that Ortho Biotech's pricing evinces any sort of deliberate plan to inflate AWP (adapted from Hartman Liability Report, Attachment I.4):

Procrit Spreads > 30% (Per Hartman Liability Report)

Procrit NDC	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003													
00062740103													
00062740201													
00062740501													
59676030201			X										
59676030202						X						X	X
59676030301													
59676030302						X						X	
59676030401			X										
59676030402													
59676031001					X								
59676031002								X	X				
59676031201						X	X						
59676032001							X	X	X				
59676034001													X

Moreover, a careful review of Procrit's pricing data reveals that the spread calculations done by Dr. Hartman's staff were not done in complete accordance with Dr. Hartman's instructions. Dr. Hartman intended to remove from his calculations all sales (and discounts) to

the government, managed care entities, and hospitals, because none of them pay based on AWP. Hartman Liability Report, ¶ 61. But not all such sales were removed. When the spreads are recalculated with those sales removed, ***only one spread out of 116 exceeded 30%,*** and even that isolated figure may reflect anomalies in the data, rather than genuine price reductions (Dukes Decl., ¶ 30, Exh. 6):

Procrit Spreads > 30% (Corrected)

Procrit NDC	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003													
00062740103													
00062740201													
00062740501													
59676030201													
59676030202													
59676030301													
59676030302													
59676030401			X										
59676030402													
59676031001													
59676031002													
59676031201													
59676032001													
59676034001													

Even if the Court were to accept Dr. Hartman's calculations as true, summary judgment would still be necessary. A random handful of spreads greater than 30% cannot be sufficient to make out a prima facie case that the J&J Defendants misled or deceived anyone. Plaintiffs' theory that defendants tried to buy market share by creating huge spreads has no conceivable application to a drug like Procrit.

Moreover, there is no evidence that small, incremental differences above 30% on selected Procrit NDCs had any affect on physicians or caused injury to class members. For example, there is no evidence, nor could there be, that physicians administered more Procrit in 1995 because the spread on one of Procrit's NDCs was 30.3%, instead of 30%. Yet because that small

increase takes the spread over Dr. Hartman's "speed limit," plaintiffs claim a fraud resulting in damages to "National Third Party Payors" of nearly $2.8 million. Hartman Liability Report, Attachment J.4.d.

Finally, there is absolutely no evidence that Ortho Biotech's price increases were fictitious. To the contrary, whenever Ortho Biotech raised Procrit's list price (thereby raising its AWP) a substantial segment of Ortho Biotech's customers (*e.g.*, retail drug stores) paid the higher price. Hiriak Decl., ¶ 21. Procrit's price increases were real, as evidenced by the fact that Procrit's ASP and list price were closely correlated. Dukes Decl., ¶ 33, Exh. 7b.

C. There Is No Admissible Evidence that a Class 1 Representative Was Ever Administered or Paid for Procrit Based on Procrit's AWP

1. There Is No Admissible Evidence that Mr. Shepley Was Ever Administered Procrit

James and Theresa Shepley are Class 1 representatives for the claims against Procrit. Mr. Shepley was treated for prostate cancer at the Alpine Hematology Oncology clinic (the "Alpine Clinic") in Reno, Nevada. Declaration of Donald E. Haviland, Esquire in Support of Plaintiffs' Memorandum in Support of Proposed Consolidated Class Certification Order ("Haviland Decl."), Exhibit M (Dec. 15, 2005) (Schau Decl., Exh. 10). According to Mr. Shepley's medical records he was administered "EPOGEN 1000U" on September 10 and September 17, 2004, for which he was "charged" $780.00. *Id.*, Exhibit M at SHEPLEY 12. Mr. Shepley's medical records make no reference to Procrit.

Procrit is manufactured by Amgen, Inc. It is sold by Ortho Biotech under license from Amgen. Amgen sells its own brand of epoetin alfa under the brand name Epogen®. Hiriak Decl., ¶ 7; Complaint, ¶ 422.

Although Procrit and Epogen are identical, and carry the same FDA-approved indications, pursuant to the parties' license agreement, Amgen markets Epogen for anemia

associated with dialysis treatment, whereas Ortho Biotech markets Procrit for anemia associated with conditions other than dialysis. Physicians, however, can and do use either brand for any approved indication. Hiriak Decl., ¶ 9; Complaint, ¶ 422 at n.6.

Mr. Shepley's medical records plainly state that he received Epogen, not Procrit. Plaintiffs contend that the references to "EPOGEN 1000U" are incorrect. They base this assertion on a hearsay statement contained in a letter that Mr. Shepley's lawyers solicited from the Alpine Clinic in November 2005, more than a year after Mr. Shepley's treatment. In response to counsel's letter, someone named Irene Sandell filled in a blank indicating that the epoetin alfa Mr. Shepley received was "manufactured" by Ortho Biotech. Haviland Decl., ¶ 37, Exhibit M at SHEPLEY 0041.

Ms. Sandell's response to counsel's letter is inadmissible hearsay, and as such is insufficient to raise a triable issue of fact. *See, e.g., Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990) ("Hearsay evidence, inadmissible at trial, cannot be considered on a motion for summary judgment."). The unreliability of this hearsay statement is apparent. All of the epoetin alfa sold in the United States, including Procrit, is manufactured by Amgen, not by Ortho Biotech. Hiriak Decl., ¶ 7.

2. There Is No Admissible Evidence that Mr. Shepley Paid for Epoetin Alfa Based on Procrit's AWP

The clinic's $780 "charge" for "EPOGEN1000U" bears no apparent relationship to Procrit's AWP. In 2004, the year Mr. Shepley received epoetin alfa, none of Procrit's published AWPs for any of its various NDCs bore any discernable relationship to the $780 charge amount.[10] Similarly, Procrit's AWPs do not bear any apparent relationship to the Shepley's

[10] Procrit's AWPs in 2004 were $144.00, $160.27, $176.28, $216.00, $240.41, $264.36, $288.00, $320.54, $352.50, $667.80, $720.00, $734.50, $801.36, $881.28, $1,001.70, $1,101.50, $1,335.60,

$132.60 payment, or to the $56.60 amount his counsel says represents Mr. Shepley's "co-insurance amount for Procrit®." Haviland Decl., ¶ 35. Thus, the record contains no admissible evidence that the clinic's $780 "charge" was based on Procrit's AWP, or that the Shepley's $132.60 payment was based on Procrit's AWP.

3. The Procrit Class Representatives Cannot Make Out a Prima Facie Case

The Shepleys are residents of Nevada. Under the relevant Nevada statute, Mr. and Mrs. Shepley may not bring a claim unless they were "victims" of a "consumer fraud." NEV. REV. STAT. § 41.600; *See Rebel Oil Co. v. Atlantic Richfield Co.*, 828 F. Supp. 794, 797 (D. Nev. 1991).

The Shepleys cannot prove they were "victims" of a consumer fraud relating to Procrit, because there is no admissible evidence Mr. Shepley received Procrit or paid for Procrit based on Procrit's AWP. Mr. Shepley does not even claim he was overcharged for Procrit.

> Q. In this lawsuit are you claiming that you were overcharged for a drug called Procrit?
>
> A. No.
>
> * * *
>
> MR. HAVILAND: Do you understand her questions? Do you understand what she is asking you?
>
> A. Yes.[11]

Moreover, there is no evidence the Shepleys were ever exposed to or made aware of Procrit's AWP. Nevada does not recognize fraud claims by consumers who never saw, read, or received the challenged statement. *Scaffidi v. United Nissan*, No. CV-S-04-1366, 2005 WL 3737892, *7 (D. Nev. Dec. 30, 2005) (summary judgment in favor of defendant on consumer

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$1,468.75, $1,602.72, $1,762.50, $2,136.96, $2,350.00, $3,339.00, and $3,672.00. Plaintiffs' Supplemental Response to J&J Defendants' Requests for Admission and Interrogatories Concerning Procrit, Exh. A.

[11] Deposition of James Shepley at 51:22 – 52:8 (Nov. 11, 2005) (Schau Decl., Exh. 11).

fraud claim is proper where "[t]here is no evidence that at any time [defendant] made a false statement to, or for that matter communicated with, [plaintiff] in the course of its business.") (Schau Decl., Exh. 15).

Finally, the Shepleys cannot prove they were "victims" of a consumer fraud relating to Procrit, because even if Mr. Shepley received Procrit, there is no evidence that he received one the NDCs with a spread allegedly greater than 30%.

* * *

In light of the foregoing, the claims of these particular class representatives should be dismissed. But given Procrit's modest spreads overall, it is abundantly clear that the claims of the class as a whole must also be dismissed.

II. PLAINTIFFS CANNOT MAKE OUT A PRIMA FACIE CASE OF "AWP FRAUD" RELATING TO REMICADE

A. Remicade Would Not Have Been Utilized If the Published AWP Had Been Equal to the Average Selling Price

Centocor introduced Remicade in 1998. It revolutionized the treatment of rheumatoid arthritis. Declaration of John Hoffman ("Hoffman Decl."), ¶ 5.

When Remicade was introduced, Medicare was reimbursing at 95% of AWP, and state Medicaid agencies were reimbursing at substantial discounts below AWP.[12] Because these programs were reimbursing at less than AWP, Centocor could not have recommended an AWP that equaled Remicade's acquisition cost. Had it done so, physicians would have needed to pay more for Remicade than they received in reimbursement.

[12] 42 U.S.C. § 1395u(o); Memorandum from HCFA, Region VI to Office of the Director, Bureau of Eligibility, Reimbursement and Coverage, HHS (March 10, 1988) (Fowler Decl., ¶ 9, Exh. 8).

Remicade came to market at a time when rheumatologists typically lacked the resources to perform infusion services and were unfamiliar with the practice of purchasing drugs and administering them to their patients. Hoffman Decl., ¶¶ 32, 34. The financial and logistical obstacles to in-office infusion were substantial. Before physicians could administer Remicade in the office they needed to purchase infusion equipment, hire and train the necessary personnel, acquire and set aside additional office space, and incur the various other costs and risks associated with in-office infusions. *Id.* Without a reasonable margin, physicians could not have covered their costs and would never have purchased and infused Remicade in their offices. Instead, patients would have been relegated to hospitals – a more costly and inconvenient venue. An average infusion of Remicade in a physician's office would cost payors $1,342, whereas an infusion in the hospital would cost payors between $1,522 and $5,588. *Id.*, ¶ 39.

B. Remicade's Pricing Was Not Unlawful

1. Remicade's Pricing Was Transparent Because Centocor Did Not Offer Price Incentives to Providers

Plaintiffs' fraud claim supposes that payors were deceived because they did not know the magnitude of the "secret" discounts that providers receive from manufacturers, and that their ignorance of the real price caused them to overpay.[13] Plaintiffs' theory has no conceivable application to Remicade, because Centocor did not give "secret" price incentives to physicians. Hoffman Decl., ¶ 21. In fact, Centocor did not give ***any*** discounts or rebates to physicians. *Id.* As a result, Remicade's pricing as reported by the pricing services was transparent. Remicade's complete, published pricing history is summarized in the following table (*Id.*, ¶ 16):

[13] *See, e.g.*, Hartman Class Cert. Report, Attachment C, ¶ 35 ("The spread must be increased secretly, because if such spreads were understood to exist, competitors would behave to eliminate them.").

Time Period	Published List Price	Published AWP	AWP % Above List Price
Launch – June 18, 1999	$450.00	$585.00	30%
June 19, 1999 – March 31, 2000	$470.25	$611.33	30%
Apr. 1, 2000 – Nov. 3, 2000	$493.29	$641.28	30%
Nov. 4, 2000 – June 6, 2001	$512.04	$665.65	30%
June 7, 2001 – Present	$532.00	$691.61	30%

These published prices tell the entire story. Remicade's published list price did not merely "signal" the price at which providers could purchase the drug, for all practical purposes it ***was*** the price at which providers could purchase the drug. Centocor sold Remicade to wholesalers and specialty distributors at the published list price, less an industry-standard prompt pay incentive and, in the case of specialty distributors, a small service fee. *Id.*, ¶¶ 18-19. Because physicians did not receive additional price incentives, their cost of acquiring Remicade was approximately the same as Centocor's published list price.

In fact, the only price incentives Centocor gave on Remicade were those it offered to *payors*, such as health plans and managed care organizations. These price incentives had the effect of *reducing* the payors' net reimbursement cost. *Id.*, ¶ 26-27.

2. Remicade's Spreads Were Modest

As the Court intimated at the class certification hearing, Remicade's modest spreads make it an ideal candidate for summary judgment. The difference between the physician's acquisition cost and the published AWP was at or below 30%. Hoffman Decl., ¶¶ 28-30. This is hardly the sort of "dramatic" spread that the Court seemed to think might warrant an inference that payors might have been deceived. Nor was this "spread" a secret.

When Dr. Hartman's staff attempted to calculate the difference between Remicade's published AWP and its average selling price they concluded that it was modestly higher than 30% (Hartman Liability Report, Attachment G.4.c.):

Remicade Spreads Per Dr. Hartman's Dec. 2005 Report					
1998	1999	2000	2001	2002	2003
30.8%	33.4%	31.9%	36.1%	33.9%	34.3%

However, Dr. Hartman's staff did not exclude all sales to government entities and managed care as Dr. Hartman had instructed. Dukes Decl., ¶ 49, Exh. 14. They also included the service fees that Centocor paid to specialty distributors. Including service fees in the ASP calculations underscores why ASP is a poor surrogate for a physician's actual acquisition cost. The service fees paid to specialty distributors, much like prompt pay discounts, are not price incentives to physicians, and there is no evidence that they are passed on to the physicians. Hoffman Decl., ¶¶ 18-19. When the appropriate transactions are removed from the calculations the "spread" between Remicade's ASP and AWP is 30% (Dukes Decl., ¶ 32, Exh. 6):

Corrected Remicade Spreads					
1998	1999	2000	2001	2002	2003
30%	30%	30%	30%	30%	30%

But the true difference between reimbursement cost and acquisition cost is even lower. As noted, Centocor paid rebates to payors such as managed care organizations and health plans. These payors benefit from the rebates they receive because the rebates lower their cost of reimbursement. If these rebates are treated like a credit against the reimbursement amount, which is how they should be treated, the Remicade "spreads" in 2001 through 2003 were less than 30% (Dukes Decl., ¶ 56):

Corrected Remicade Spreads (Less Payor Rebates)					
1998	1999	2000	2001	2002	2003
30%	30%	30%	29.9%	29.4%	28.4%

But even if one were to ignore economic reality and adopt Dr. Hartman's spread calculations at face value, Remicade's modest spreads do not evidence any sort of secret or

unlawful manipulation of AWP. This is particularly true because Remicade's *published* spread was 30%. Significantly, Dr. Hartman admits that (1) payors were fully aware of, and paid attention to, the published differences between AWP and list price, and (2) they fully understood that discounts below the published list prices were commonplace. Hartman Dep. at 678, 682, 683-85.

These two admissions are fatal to plaintiffs' claim against Remicade. Plaintiffs have painted themselves into a corner. Since payors knew that the published spread was 30%, and since payors expected that there might be additional discounts, plaintiffs' claim fails, even under their own theory, unless they can prove that that the small, incremental differences between Remicade's actual spread (*e.g.*, 30.8% in 1998 and 31.9% in 2000) and its published spread of 30% were somehow unexpected. In effect, plaintiffs must demonstrate that ***any*** unreported discount, no matter how small, is fraudulent. That is not the law. *See, e.g.*, *Whitehall Co. v. Barletta*, 404 Mass. 497, 503, 536 N.E.2d 333 (1989) (nondisclosure of discount does not violate Mass. G.L. ch. 93A).

In fact, plaintiffs have no evidence that any real person or payor was ever deceived by Remicade's pricing. There is no claim that Centocor increased Remicade's list price (and, consequently, its AWP) while simultaneously lowering its actual selling prices. In fact, Remicade's list price stayed the same for four years and then, when the list price was eventually increased, physicians paid the higher price because they were not given discounts or rebates. As a result, Remicade's ASP closely tracked its list price. *See* Dukes Decl., ¶ 33, Exh. 7d.

Given the fatal defects in their Remicade pricing case, plaintiffs will likely resort to arguing that Centocor "marketed the spread." This argument does nothing to advance plaintiffs' fraud claim. Plaintiffs' own expert, Dr. Rosenthal, concedes that whether or not a company

"markets the spread" is irrelevant. Deposition of Meredith Rosenthal, Ph.D. at 486:16-487:4 (Feb. 23, 2006) (Schau Decl., Exh. 12). In her opinion, it is only the existence of an actionable spread that matters. As she puts it, "marketing the spread" is just a term "the lawyers" use. *Id.*

As noted above, Centocor had legitimate, good faith reasons to speak with physicians about the practical aspects of in-office infusion, including the potentially positive financial implications for the physician's practice. Hoffman Decl., ¶ 32. In-office infusion entails significant costs and risks. It was essential that rheumatologists be able to earn a margin over acquisition cost. *Id.*

Centocor promoted office-based infusion as a less costly alternative to infusion in hospitals. Centocor made presentations to health plans highlighting the cost savings they could achieve if Remicade were administered in the physician's office. Several health plans cooperated with Centocor in its effort to persuade physicians that they should infuse Remicade themselves rather than send their patients to the hospital. Indeed, some health plans reported receiving bills from hospitals that were several thousand dollars above the cost of the drug. *Id.*, ¶ 40.

Accurate and truthful discussions of the difference between Remicade's acquisition price and its reimbursement amount are protected "commercial speech" under the First Amendment to the United State Constitution. *See El Dia v. Puerto Rico Dep't of Consumer Affairs*, 413 F. 3d 110, 113 (1st Cir. 2005) citing *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557 (1980).

C. Mrs. Young's Estate Does Not Have a Claim Under Oklahoma Law

1. There Is No Admissible Evidence that Mrs. Young Paid for Remicade Based on Remicade's AWP.

The Court certified the Estate of Patricia Young as a Class 1 representative against Centocor, Inc. and Johnson & Johnson. Mrs. Young started receiving Remicade in 2002, and continued to receive it until she passed away in 2004. Deposition of Larry Young ("Young Dep."), at 78-79 (Nov. 9, 2005) (Schau Decl., Exh. 13). Throughout this time period, Remicade's AWP was $691.61 per 100 mg vial.[14]

Mrs. Young's Remicade infusions were covered by Medicare Part B, and her co-payment obligations were covered by supplemental insurance. *E.g.*, Complaint, ¶ 21; Young Dep. at 10-11. Mrs. Young's sole financial obligation was to pay the deductible amount specified in her insurance contract, up to an annual limit of $1,190. Haviland Decl, Exh. Q at YOUNG 0035. Mrs. Young made no payments for Remicade other than payments toward this fixed deductible amount, which related to other services as well. Young Dep. at 99-100, 167.

There is no evidence that Mrs. Young's deductible payment was based on Remicade's AWP. Mr. Young testified that he does not know how the deductible amount was determined. Young Dep. at 20. The $1,190 deductible amount bears no discernable relationship to Remicade's $691.61 AWP (or to any multiple thereof), or to a co-payment equal to 20% of either 95% or 85% of Remicade's AWP.

Accordingly, there is no evidence that Mrs. Young paid for Remicade based upon Remicade's AWP.

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[14] *See* Plaintiffs' Supplemental Response to J&J Defendants' Requests for Admission and Interrogatories Concerning Remicade, Exhibit A (Schau Decl., Exh. 14).

2. The Oklahoma Consumer Protection Act Does Not Apply To Transactions Regulated Under Federal Law

Mrs. Young was a resident of Oklahoma. Oklahoma's consumer protection statute exempts transactions regulated under federal law. Consequently, her Estate's claim fails as a matter of law.

Plaintiffs contend that AWPs are regulated by federal law and that they are supposed to equal ASP "by statute."[15] Although defendants disagree with plaintiffs' interpretation of federal law, it is undisputed that, during the class period, the government's AWP-based reimbursement formula was codified in the federal statute and federal regulations. As this Court has explained, "[u]nder the fee-for-service program, Medicare Part B reimburses for drugs based on formulae set by federal statute and federal regulations."[16]

Although AWP is not "defined" in any federal statute or regulation,[17] the fact that its use is codified and regulated under federal law is an absolute bar to the Estate's claims. By its terms, the Oklahoma Consumer Protection Act does not apply to "[a]ctions or transactions regulated under laws administered by . . . any . . . regulatory body or officer acting under statutory authority of . . . the United States." 15 OKLA. STAT. tit. 15, § 754 (emphasis added); *Patterson v. Beall*, 19 P.3d 839, 847 n.13 (Okla. 2000).

The "actions or transactions" at issue in this case, namely Estate of Young's alleged overpayment payment for the 20% co-payment under the Medicare Part B program for Remicade because of its allegedly "false and inflated" AWP, fall squarely within the Oklahoma exemption,

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[15] Hartman Liability Report ¶¶ 19-20.

[16] *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 230 F.R.D. at 70-71 (Memorandum and Order Re: Motion for Class Certification) (citing 42 U.S.C. §§ 1395u(o) & 13951(s) and 42 C.F.R § 405.517).

[17] *See* Track 1 Memorandum.

because Medicare Part B transactions are regulated under laws administered by CMS, which acts under statutory authority of the United States. *See Brice v. AT&T Communications, Inc.*, 32 P.3d 885, 887 (Okla. Civ. App. 2001) (reversing summary judgment against a telephone company on a rate dispute asserted under the OCPA because the telephone company, whose rate-setting is subject to the Oklahoma Corporation Commission's rules and regulations, was exempt from liability under the OCPA); *see also Wash. Osteopathic Med. Ass'n v. King County Med. Serv. Corp.*, 478 P.2d 228, 230 (Wash. 1970) (holding that allegedly anti-competitive transactions were exempt from liability under the state's consumer-protection law because the transactions were subject to regulation by the state's insurance commissioner).

3. Centocor's Conduct Does Not Satisfy the Elements of a Claim Under the Oklahoma Consumer Protection Act

A consumer seeking redress under the Oklahoma Consumer Protection Act must prove each of the following elements:

> (1) that the defendant engaged in an unlawful practice as defined – at 15 Okla. Stat. § 753 (1991); (2) that the challenged practice occurred in the course of defendant's business; (3) that the plaintiff, as a consumer, suffered an injury in fact; and (4) that the challenged practice caused the plaintiff's injury.

Patterson, 19 P.3d at 846. The Act prohibits 29 enumerated practices plus a catch-all. 15 OKLA. STAT. tit. 15, § 753; *see also Patterson*, 19 P.3d at 846. The only practice that might conceivably apply to Centocor's alleged AWP scheme would be the catch-all provision, which prohibits "an unfair or deceptive trade practice as defined in Section 752 of this title." *Id.* § 753(20).

Section 752 defines a "deceptive" trade practice as "a misrepresentation, omission or other practice that has deceived or could reasonably be expected to deceive or mislead a person to the detriment of that person." 15 OKLA. STAT. tit. 15, § 752(11). It defines an "unfair" trade practice as "any practice which offends established public policy or if the practice is immoral,

unethical, oppressive, unscrupulous or substantially injurious to consumers." *Id.* § 752(12). The Oklahoma Supreme Court has held that a plaintiff does not state a claim unless the allegedly false statements "have the capacity to ***deceive the consumer***." *Patterson*, 19 P.3d at 847 n.12 (emphasis added).

Plaintiffs do not allege that Centocor's AWPs deceived "consumers." Nor do they allege that consumers were deceived by the small, incremental differences between Remicade's published spread of 30%, and its alleged "real" spread, which was modestly higher than 30%. In fact, plaintiffs make no claim that Oklahoma consumers ever saw Centocor's AWPs, and they offered no proof that Mrs. Young was exposed to or deceived by Remicade's AWP.

Plaintiffs' Class 1 and Class 2 claims are instead premised on the theory that these class members were foreseeable victims of a fraud perpetrated on the federal government. Existing Oklahoma precedent on deceptions directed to "a person to the detriment of that person" and on practices that "deceive the consumer" suggests that the Oklahoma courts, like the Nevada courts, would reject a consumer fraud claim where the consumer never saw, read, or received the challenged statement.

CONCLUSION

The J&J Defendants respectfully request that their motion for summary judgment be granted as to Class 1 and Class 2.

Dated: March 15, 2006

/s/ William F. Cavanaugh, Jr.

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